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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,830	01/30/2002	Yizhong Gu	PB0169	3442

7590

11/12/2004

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EXAMINER

SWOPE, SHERIDAN

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/060,830	Applicant(s) GU, Y. ET AL	
	Examiner Sheridan L. Swope	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-47 is/are pending in the application.
- 4a) Of the above claim(s) 13-31, 34-38 and 40-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-12, 32, 33, and 39 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Applicant's response, of September 7, 2004 to the Action on the Merits of this case mailed March 31, 2004, is acknowledged. It is acknowledged that applicants have amended Claim 1 and cancelled Claims 48 and 49. Claims 1 and 3-47 are pending. Claims 13-31, 34-38, and 40-47 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Inventions, there being no allowable generic or linking claim. Claims 1, 3-12, 32, 33, and 39 are hereby reconsidered.

Claim Rejections - 35 USC § 101

Rejection of Claims 1, 3-12, 32, 33, and 39 under 35 U.S.C. § 101 because the claimed invention lacks patentable utility, for the reasons described in the actions of February 5, 2003, July 29, 2003, and March 31, 2004, is maintained.

In support of their request that said rejection be withdrawn, Applicants provide the following arguments.

(1) The recited nucleic acid molecules encode proteins having a transmembrane domain, a signal peptide, an LCCL domain, a discoidin domain, a truncated CUB domain, and an extracellular domain.

(2) Mutation in the LCCL domain of another protein cause the deafness disorder DFN9.

(3) The recited nucleic acid molecules and encoded polypeptides are useful in developing therapeutics as well as diagnostic for neurological and developmental disorders and tumors.

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(4) It is well established that one can use a gene sequence in disease diagnosis, prognosis, and in the development of therapeutics and treatment.

(5) Gene sequences can be used as substrates on microarrays for expression analysis in cancer patients or patients with developmental disorders. The sequences can also be used as antisense inhibitors of the over-expressed genes in patients as well as to produce the encoded proteins antibodies or fusion proteins. In addition, the nucleic acid sequences can be used to develop primers and probes.

These arguments are not found to be persuasive for the following reasons.

(1) Reply: The fact that the recited nucleic acid molecules encode proteins having a transmembrane domain, a signal peptide, an LCCL domain, a discoidin domain, a truncated CUB domain, and an extracellular domain does not support a specific and substantial utility for said nucleic acid molecules because many proteins have said domains and neither the prior art nor Applicant's specification points to any specific use found in all proteins comprising these domains.

(2) Reply: Because mutation in the LCCL domain of another protein causes a deafness disorder would not convince one of skill in the art that mutation of the LCCL domain of the protein encoded by the recited polynucleotide causes a deafness disorder.

(3) Reply: The specification fails to assert that the recited nucleic acid molecules or the encoded polypeptides can be used for the treatment or diagnosis of any specific disorder. Furthermore, neither the specification nor the prior art support any said use.

(4) Reply: It is acknowledged that that one can use some gene sequences in disease diagnosis, prognosis, and in the development of therapeutics and treatment. However, see (3).

(5) Reply: Regarding a use in microarrays for expression analysis in cancer patients or patients with developmental disorders, see (3). Regarding the use as antisense inhibitors, to produce the encoded proteins, antibodies, or fusion proteins or as primers or probes, each of these utilities is an application that would apply to every member of a general class of materials and/or is a use only for further research to determine a use for the recited polynucleotide or the encoded protein. As such, these asserted utilities are not specific (for those applicable to all human polynucleotides) or not substantial because the use of said polynucleotides and proteins therein is only potential and not in currently available in practical form.

Rejection Claims 1, 3-12, 32, 33, and 39 under 35 U.S.C. § 112, first paragraph, for lack of enablement is also maintained. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility, for the reasons set forth above and in the prior actions, one skilled in the art clearly would not know how to use the claimed invention.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943.

The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan Lee Swope, Ph.D.


REBECCA E. PROUTY
PRIMARY EXAMINER
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1600